# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

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## I. GENERAL INFORMATION

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| **Device Generic Name** | PDT Balloon Catheter and Light Delivery System, Photodynamic Therapy |
| **Device Trade Name** | Wizard X-Cell™ Photodynamic Therapy Balloon with Fiber Optic Diffuser |
| **Applicant's Name and Address** | Axcan Scandipharm, Inc.<br>22 Inverness Center Parkway<br>Suite 310<br>Birmingham, Alabama 27105 |
| **Date of Panel Recommendation:** | June 26, 2003 |
| **Premarket Approval Application (PMA) Number** | P020021 |
| **Date of Notice of Approval to Applicant** | August 1, 2003 |

## II. INDICATIONS FOR USE

The Wizard X-Cell™ Photodynamic Therapy Balloon with Fiber Optic Diffuser is intended for use in Photodynamic Therapy (PDT) with the appropriate laser source for the delivery of light for the photoactivation of Photofrin® (porfimer sodium) for Injection for the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

## III. DEVICE DESCRIPTION

The Wizard X-Cell™ Photodynamic Therapy Balloon with Fiber Optic Diffuser is composed of the Wilson-Cook PDT Balloon Catheter and a fiber optic diffuser. The Wilson-Cook catheter is a non-sterile, disposable balloon catheter consisting of a PET balloon with reflective coated end caps, a coaxial catheter shaft and proximal extension lines for balloon inflation and fiber optic passage. It is designed for passage of the fiber optic and to direct and intensify light energy from the fiber optic in the esophagus during Photodynmaic Therapy (PDT) of Barrett's Esophagus. The output of the balloon catheter assembly is a cylindrical distribution of light along the length

of the treatment window of the balloon. The light is emitted by the fiber optics cylindrical diffuser inserted into the inner lumen of the catheter shaft.

The fiber optic diffuser is a 400 μm coated silica cylindrical treatment fiber assembly that can be connected directly to lasers used for PDT. It contains a proximal SMA-type laser connector and a distal light diffusing tip. The device does not change the energy output and is only intended to act as a conduit. The output of this probe assembly is a cylindrical distribution of light along the length of the distal tip of the probe. The tip is configured to allow treatment within a lumen, in the balloon window.

A kit is provided with this system which includes a fiber optic positioning device, which is used to position the fiber optic diffuser in the balloon catheter, and a Touhy-Borst Adapter. The Touhy-Borst Adapter is attached to the proximal end of the balloon catheter, and is used to set the appropriate distance for the fiber optic diffuser to assure it is centered in the treatment window upon insertion.

## IV. ALTERNATIVE PRACTICES AND PROCEDURES

Esophagectomy currently constitutes a proposed standard practice of care. There is substantial debate concerning the management of patients whose endoscopic biopsies show high-grade dysplasia (HGD) without adenocarcinoma. Another approach is continued endoscopic surveillance until biopsy evidence of esophageal cancer is found.

## V. MARKETING HISTORY

The Wizard X-Cell™ Photodynamic Therapy Balloon with Fiber Optic Diffuser has not been commercially distributed.

## VI. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

For a list of adverse events observed in the clinical study, please refer to the Photofrin label. Adverse effects associated with the Wizard X-Cell™ PDT Balloon with Fiber Optic Diffuser could be related to the potential complications associated with upper GI endoscopy including, but not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

Besides the potential adverse events directly associated with the device as a catheter system, there are additional potential adverse effects that could be associated with either excess or too little light delivered. Too little light delivery could result in under treatment resulting in little or no therapeutic

benefit for the patient. Over exposure of light could result in thermal damage to the esophagus resulting in esophageal burns or unwanted tissue necrosis.

## VII. SUMMARY OF PRECLINICAL STUDIES

Non-clinical studies involving the Wizard X-Cell™ PDT Balloon with Fiber Optic Diffuser included engineering studies designed to confirm manufacturing process and optical equivalence of the Optiguide Fiber Optic Diffusers, and animal studies designed to demonstrate the safety and potential effectiveness of the Wizard Balloon when used in treating Barrett's Esophagus. The engineering studies have demonstrated that the optical output in terms of energy and spectral scan are identical using either the DCYL 3 or DCYL 5 series of Optiguide Fiber Optic Diffusers. Both of these series diffusers were used in the clinical study.

The animal studies involved the use of dogs who received IV injections of Photofrin. The animals had their esophagus exposed to light using the Wizard Balloon. These studies did demonstrate that the Balloon did not, by itself cause unacceptable tissue damage and when used with the appropriate light source could be used to deliver uniform light exposure the esophageal tissues.

## VIII. SUMMARY OF CLINICAL STUDIES

The results of the clinical studies for the Wizard X-Cell™ PDT Balloon Catheter with Fiber Optic Diffuser in photodynamic therapy for the ablation of high-grade dysplasia in Barrett's esophagus patients who do not under go esophagectomy are presented in the PHOTOFRIN NDA 21-525. A summary of this data is contained in the labeling for PHOTOFRIN.

## IX. CONCLUSIONS DRAWN FROM STUDIES

The in vivo and engineering non-clinical studies together with the clinical investigation reported in NDA 21-525 provide valid scientific evidence and provide reasonable assurance that the Wizard X-Cell™ Photodynamic Therapy Balloon with Fiber Optic Diffuser is safe and effective for delivering the required activation light for use with PHOTOFRIN® (porfimer sodium) for Injection for the specified indication for use when used in accordance with the labeling for PHOTOFRIN and the OPTIGUIDE Fiber Optic Diffusers.

## X. PANEL RECOMMENDATION

The clinical data provided by the company to support the indication for use being requested was reviewed by the Gastrointestinal and Coagulation Drugs Advisory Panel, CDER on June 26, 2003. The panel recommended approval of the combination drug/device system for the indication for use of ablation of

high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

## XI. CDRH DECISION

CDRH concurred with the Gastrointestinal and Coagulation Panel recommendation of June 26, 2003 and issued an approval order on August 1, 2003. The device manufacturing facilities were inspected and found to be in compliance with the Quality System Regulation (21 CFR 820).

## XII. APPROVAL SPECIFICATIONS

Information on the use of the Wizard X-Cell™ Photodynamic Therapy Balloon with Fiber Optic Diffuser is found in the Operator Manual. Instructions for the use of the laser system to be used with this system can be found in the laser system Operator Manual and in the Photofrin® Package Insert. Instructions for the use of this device with Optiguide Fiber Optic Diffusers can be found in the Optiguide Package Insert.